IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. James Rice, M.D.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Plaintiffs' Motion to Exclude Opinions and Testimony of James Rice, M.D [ECF No. 4830]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' Motion is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the Boston Scientific Corp. ("BSC") MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis.

To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, http://www.wvsd.uscourts.gov/MDL/boston/orders.html. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Rice is a urogynecologist retained by BSC to offer opinions relating to mesh generally and BSC's Solyx product in particular. He is an Associate Clinical Professor of Obstetrics and Gynecology at the University of Washington and has an active clinical practice.

A. Safety and Efficacy

First, plaintiffs challenge the reliability of Dr. Rice's opinion that the Solyx is a safe and effective treatment for SUI because he ignored peer-reviewed medical literature supporting a different conclusion. The plaintiffs cite a study they believe Dr. Rice ignored, and about which they questioned him at his deposition. Dr. Rice explained, however, why he did not believe the study was relevant or contrary to his opinion. Although an expert's opinion may be unreliable if he fails to account for contrary scientific literature and selectively chooses his support from the scientific landscape, that is not the case in this instance. The plaintiffs' Motion is **DENIED** on this point.

B. Material Safety Data Sheet ("MSDS")

Second, plaintiffs object to Dr. Rice's opinions regarding the MSDS for Marlex—specifically, that Dr. Rice has "never consulted an MSDS for the purpose of evaluating the safety and efficacy of a medical device or treating, advising, or counseling a patient" and that doctors generally do not review or rely on the MSDS in their practices. Rice Report 17. Dr. Rice's opinions on his and other doctors' experience with the MSDS for raw polypropylene pellets is not relevant or helpful to the jury. The pertinent issue is not whether doctors rely on or heed MSDS warnings for the raw materials BSC uses to manufacture its medical devices. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 577 (S.D. W. Va. 2014) (excluding a doctor's opinions on the MSDS because "[a] narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury"). Nevertheless, I

acknowledge the need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Rice's MSDS opinions for trial.

C. Adequacy of Warnings

Third, plaintiffs challenge the reliability of Dr. Rice's opinions about the adequacy of the Solyx Directions for Use ("DFU") and his qualifications to offer such opinions. The two arguments are intertwined, and I treat them here together. The plaintiffs argue that Dr. Rice has no knowledge or experience working on or drafting DFUs. BSC does not dispute this deficiency, but states Dr. Rice offers his opinions from a clinical—rather than a regulatory—perspective. BSC asks the court to allow Dr. Rice to testify about the Solyx DFU based on his "extensive training and clinical experience." I have repeatedly ruled that, without additional expertise in the specific area of product warnings, a doctor such as Dr. Rice is not qualified to opine that a product warning was adequate merely because it included risks he observed in his own practice. Accordingly, the plaintiffs' Motion is **GRANTED** on this issue, and Dr. Rice's opinions related to product labeling are **EXCLUDED**.

D. Physician Training

Fourth, plaintiffs argue that Dr. Rice's opinions regarding BSC's lack of training or instruction on mesh removal are unreliable. Dr. Rice offers the opinion that "any decision to remove pelvic mesh will be individualized and based upon physician and patient preference, the patient's tolerance for risk . . ., existing symptomology, and the patient's unique health conditions." Plaintiffs contend that

Dr. Rice does not provide "an articulable industry standard by which he judges Boston Scientific's actions regarding physician training with respect to mesh removal." BSC responds that Dr. Rice's opinion is based on his "extensive clinical experience with mesh slings." I **RESERVE** ruling on the admissibility of this opinion for trial.

E. Legal Conclusions

Fifth, plaintiffs contend that Dr. Rice seeks to offer testimony constituting various legal opinions. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "adequately warned," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008). Thus, to the extent that Dr. Rice's opinions constitute legal conclusions, those opinions are **EXCLUDED**. The plaintiffs' Motion is **GRANTED** on this point.

F. Undisclosed Opinions

Finally, plaintiffs argue that Dr. Rice seeks to offer opinions based on sources not referenced in his expert report, including undisclosed BSC internal documents, deposition testimony of an unspecified BSC corporate witness, and expert reports by other experts in this litigation.

Rule 26 of the Federal Rules of Civil Procedure requires an expert report to contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Rule 37 provides that the court may exclude evidence not properly disclosed under Rule 26 unless the non-disclosing party demonstrates the Rule 26 violation was "substantially justified or harmless." Fed. R. Civ. P. 37(c)(1). Here, BSC argues that Dr. Rice's omission of certain supporting references in his expert report was harmless because, among other reasons, Dr. Rice brought these documents to his deposition, where plaintiffs' counsel had the opportunity to review and ask questions related to the documents. The court agrees that this omission was harmless because it was remedied while the plaintiffs still had an opportunity to depose Dr. Rice on the substance of the documents, the documents are typical of those relied upon in this litigation, and the omission related to support for Dr. Rice's opinions rather than the opinions themselves. Accordingly, the plaintiffs' Motion as to the undisclosed basis for certain opinions is **DENIED**.

IV. Conclusion

To summarize, the plaintiffs' *Daubert* Motion concerning Dr. Rice [ECF No. 4830] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Number	Case Name
2:17-cv-00047	Long v. Boston Scientific Corporation
2:17-cv-00049	Parker et al v. Boston Scientific Corporation
2:17-cv-00294	Grigg v. Boston Scientific Corporation
2:17-cv-00304	Martinez v. Boston Scientific Corporation
2:17-cv-00307	Michael v. Boston Scientific Corporation
2:17-cv-00314	Newton v. Boston Scientific Corporation
2:17-cv-00315	Norris v. Boston Scientific Corporation
2:17-cv-00317	Norris v. Boston Scientific Corporation
2:17-cv-00318	Osborn v. Boston Scientific Corporation
2:17-cv-00325	Pick v. Boston Scientific Corporation
2:17-cv-00528	Sustaita v. Boston Scientific Corporation
2:17-cv-00534	Notestine v. Boston Scientific Corporation
2:17-cv-00536	Sutiff v. Boston Scientific Corporation
2:17-cv-00568	Mahnke v. Boston Scientific Corporation
2:17-cv-00701	Babcock v. Boston Scientific Corporation
2:17-cv-01074	Dembski v. Boston Scientific Corporation
2:17-cv-01098	Zeiter v. Boston Scientific Corporation

2:17-cv-01109	Herbert et al v. Boston Scientific Corporation
2:17-cv-01241	Tigner v. Boston Scientific Corporation
2:17-cv-01242	Evans v. Boston Scientific Corporation
2:17-cv-01243	Brown v. Boston Scientific Corporation
2:17-cv-01837	Allen v. Boston Scientific Corporation
2:17-cv-01845	Shiflet v. Boston Scientific Corporation
2:17-cv-01862	Faso et al v. Boston Scientific Corporation
2:17-cv-01900	Hauff et al v. Boston Scientific Corporation
2:17-cv-01925	Skalniak et al v. Boston Scientific Corporation
2:17-cv-01932	Peach v. Boston Scientific Corporation
2:17-cv-01938	Schroder v. Boston Scientific Corporation
2:17-cv-01939	Price v. Boston Scientific Corporation
2:17-cv-01940	Conley v. Boston Scientific Corporation
2:17-cv-01959	Lowrie v. Boston Scientific Corporation
2:17-cv-01977	Hardwick v. Boston Scientific Corporation
2:17-cv-01979	Dunford et al v. Boston Scientific Corporation
2:17-cv-01990	Hill-Sober et al v. Boston Scientific Corporation
2:17-cv-01996	Benson v. Boston Scientific Corporation

2:17-cv-02093	Pamensky Murray v. Boston Scientific Corporation
2:17-cv-02106	Wilson v. Boston Scientific Corporation
2:17-cv-02107	Ross v. Boston Scientific Corporation
2:17-cv-02110	Clark v. Boston Scientific Corporation
2:17-cv-02111	Busby v. Boston Scientific Corporation
2:17-cv-02202	Atwood v. Boston Scientific Corporation
2:17-cv-02243	Alvarado v. Boston Scientific Corporation
2:17-cv-02244	Speed v. Boston Scientific Corporation
2:17-cv-02416	Palmer v. Boston Scientific Corporation
2:17-cv-02417	Masterson v. Boston Scientific Corporation
2:17-cv-02443	Allex v. Boston Scientific Corporation
2:17-cv-02446	Blalock v. Boston Scientific Corporation
2:17-cv-02447	Casale v. Boston Scientific Corporation
2:17-cv-02448	Clark v. Boston Scientific Corporation
2:17-cv-02449	Cole v. Boston Scientific Corporation
2:17-cv-02450	Wallace v. Boston Scientific Corporation
2:17-cv-02459	Mallory v. Boston Scientific Corporation
2:17-cv-02461	Martin v. Boston Scientific Corporation

2:17-cv-02462	McSween v. Boston Scientific Corporation
2:17-cv-02467	Melrose v. Boston Scientific Corporation
2:17-cv-02470	Porter v. Boston Scientific Corporation
2:17-cv-02471	McFalls v. Boston Scientific Corporation
2:17-cv-02477	Pouncy v. Boston Scientific Corporation
2:17-cv-02481	Shepard v. Boston Scientific Corporation
2:17-cv-02483	Smith v. Boston Scientific Corporation
2:17-cv-02486	Daniell v. Boston Scientific Corporation
2:17-cv-02505	Cutlip v. Boston Scientific Corporation
2:17-cv-02508	Jeter v. Boston Scientific Corporation
2:17-cv-02524	Murphy v. Boston Scientific Corporation
2:17-cv-02525	Price v. Boston Scientific Corporation
2:17-cv-02527	Roark v. Boston Scientific Corporation
2:17-cv-02528	Saldivar v. Boston Scientific Corporation
2:17-cv-02531	Smith v. Boston Scientific Corporation
2:17-cv-02533	Southwood v. Boston Scientific Corporation
2:17-cv-02551	Solomon v. Boston Scientific Corporation
2:17-cv-02553	Spencer v. Boston Scientific Corporation

2:17-cv-02554	Stark v. Boston Scientific Corporation
2:17-cv-02562	Vincent v. Boston Scientific Corporation
2:17-cv-02566	Walker v. Boston Scientific Corporation
2:17-cv-02568	Welsh v. Boston Scientific Corporation
2:17-cv-02571	Wittenborn v. Boston Scientific Corporation
2:17-cv-02588	Adams v. Boston Scientific Corporation
2:17-cv-02589	Barnett v. Boston Scientific Corporation
2:17-cv-02590	Childress v. Boston Scientific Corporation
2:17-cv-02592	Dickeson v. Boston Scientific Corporation
2:17-cv-02596	McFolling v. Boston Scientific Corporation
2:17-cv-02597	Morgan v. Boston Scientific Corporation
2:17-cv-02598	Reid v. Boston Scientific Corporation
2:17-cv-02599	Reyes v. Boston Scientific Corporation
2:17-cv-02600	Rinaldi v. Boston Scientific Corporation
2:17-cv-02601	Woodard v. Boston Scientific Corporation
2:17-cv-02633	Pierson et al v. Boston Scientific Corporation
2:17-cv-02636	Walseth v. Boston Scientific Corporation
2:17-cv-02638	Buttke v. Boston Scientific Corporation

2:17-cv-02641	Harrison-Hood v. Boston Scientific Corporation
2:17-cv-02646	Gottfreid v. Boston Scientific Corporation
2:17-cv-02730	Black v. Boston Scientific Corporation
2:17-cv-02734	Henjum v. Boston Scientific Corporation
2:17-cv-02738	Martin v. Boston Scientific Corporation
2:17-cv-02739	Martinez v. Boston Scientific Corporation
2:17-cv-02742	Morales v. Boston Scientific Corporation
2:17-cv-02745	Shaw v. Boston Scientific Corporation
2:17-cv-02787	Stapf v. Boston Scientific Corporation